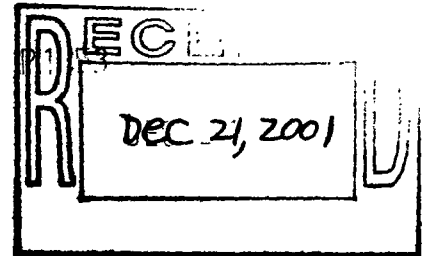


B A L C H E M C O R P O R A T I O N

PATRICIA SIUTA-CRUCE, Ph.D.
VICE PRESIDENT, TECHNOLOGY

6520 102 JAN 24
December 20, 2001



Dr. Robert Moore
Office of Nutritional Products, Labeling and Dietary Supplements
HFS-800
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835 Tel: (301) 436-2373

Re: Notification of Structure/Function Claims for a Dietary Supplement

Dear Dr. Moore:

Pursuant to our Notification letter of November 20th and in response to the Agency's reply letter from Dr. John B. Foret dated November 29 we would like to modify the two claims for our product, Vitashure® for which the Agency made reference.

In the first instance, Balchem wishes to modify the original claim "May help to reduce plasma homocysteine, a known cardiovascular risk factor" by omitting the last phrase such that the revised claim would read:

May help to reduce plasma homocysteine

For the second claim, "may help to reduce fatty deposits in the liver and liver damage", Balchem wishes to replace this claim with the following:

May promote healthy liver function

Balchem would like to take this opportunity to thank the Agency for their review of our claims and assures the Agency that by filing these claims and modifications Balchem wishes to comply to all aspects of the Agency's regulations and the Federal laws governing such Notifications.

Sincerely,

Patricia Siuta-Cruce

Patricia Siuta-Cruce, Ph.D.

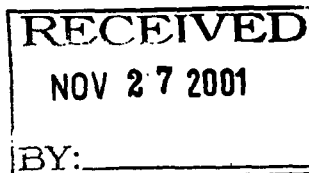
78752

97S 0162 LET 9/65 also see docket 97S-01

B A L C H E M C O R P O R A T I O N

PATRICIA SANTA-CRUCE, Ph.D.
Vice President, Technology

November 20, 2001



Dr. Robert Moore
Office of Nutritional Products, Labeling and Dietary Supplements
Room 1848
Food and Drug Administration
200 C Street
Washington, DC 20204

Tel: (202) 205-4561

Re: Notification of Structure/Function Claims for a Dietary Supplement

Dear Dr. Moore:

Pursuant to Section 403§(6) of the Federal Food, Drug, and Cosmetic Act and to 21 CFR 101.93, Balchem Corporation hereby notifies the Food and Drug Administration that it has included the following statement on the label and/or in the labeling of a dietary ingredient that Balchem manufactures and markets as a bulk material for inclusion in dietary supplement products manufactured by Balchem's customers.

The following required information is hereby provided.

- 1) Name of the manufacture, packer, or distributor of the dietary supplement that bears the statement.

Balchem Corporation (manufacturer)

- 2) The text of the statement(s) that is(are) being made.

- 1) *May help to reduce fatigue and increase vigor during strenuous exercise*
- 2) *May benefit mild memory problems associated with aging*
- 3) *May help to reduce plasma homocysteine, a known cardiovascular risk factor*
- 4) *May help to reduce fatty deposits in the liver and liver damage*
- 5) *Choline supplementation during pregnancy may lead to a lifelong improvement of visuospatial memory in children born of the pregnancy*
- 6) *Choline supplementation during infancy and childhood may help to improve lifelong memory*

- 3) The name of the dietary ingredient or supplement that is the subject of the statement.

Name of dietary ingredient: *Choline*

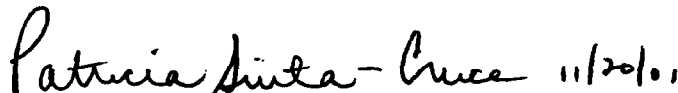
- 4) The name of the dietary supplement (including brand name), if not provided in response to paragraph (a)(2)(111) on whose label, or in whose labeling, the statement appears.

Name on label: *Choline bitartrate, Choline Chloride, or
Choline Dihydrogen Citrate*

Brand name: *Vitashure®*

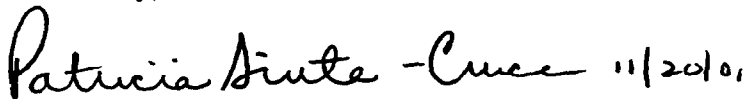
- 5) Signature of person who can certify the accuracy of information presented and contained in this notice, pursuant to 21 CFR 101.93.(a)(3)

I certify that the information contained in this notice is complete and accurate, and that Balchem Corporation has substantiation that the statement is truthful and not misleading.


Patricia Siuta-Cruce, Ph.D.
V.P., Technology
Balchem Corporation

Thank you in advance for your attention to this notice.

Sincerely,


Patricia Siuta-Cruce, Ph.D.